

### **REMARKS/ARGUMENTS**

As a preliminary matter, Applicants wish to thank the Examiner for clarification via telephone that Applicants' previously filed Interview Summary of May 12, 2006 is considered responsive to the Interview Summary attached to the Office Action of July 12, 2006 referring to a communication between the Examiner and Applicants on April 27, 2006.

Claims 42, 52, 54-60, 62-65, 67-69, 73, and 76 have been rejected. Claim 42 has been amended to remove the limitation that the targeting molecule comprises the CH2 and CH3 domains of IgA or IgM but does not comprise a full-length immunoglobulin. This limitation has been reintroduced into new claim 81. Claims 67 and 69 have been amended such that they are directed specifically to targeting molecules comprising a J chain portion encoded by nucleotides 1-213 of SEQ ID NO:8. Claim 42 has also been amended as suggested by the Examiner to remove the limitation to "an antigen combining site" (see Interview Summary attached to the Office Action of July 12, 2006). Claim 73 has been amended to depend from claim 42. Accordingly, these claim amendments do not introduce new matter.

Claims 42, 52, 54-60, 62-65, 67-69, 73, 76, and 81 are pending in the application. Reconsideration of these claims is respectfully requested in view of the aforementioned claim amendment and the following remarks. The Examiner's comments in the Office Action dated July 12, 2006 are addressed below in the order set forth therein.

#### **Maintained Double-Patenting Rejections**

Applicants note that the Examiner has maintained rejections of claims 42, 52, 54-60, 62-65, 67-69, 73, and 76 under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over the claims of co-pending U.S. Patent Application No. 08/782,481. As stated in the Amendment After Final dated May 1, 2006, when the Examiner deems the claims of the present application to be allowable except for this rejection, Applicants will file a terminal disclaimer in the present case, disclaiming any patent term beyond the term of these patents.

Applicants note that the Examiner has maintained rejections of claims 42, 52, 54-60, 62-65, 67-69, 73, and 76 under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent Nos. 6,440,419 and 7,022,309 (formerly co-

pending Application No. 10/062,467). As stated in the Amendment After Final dated May 1, 2006, when the Examiner deems the claims of the present application to be allowable except for this rejection, and when the claims of either or both of the co-pending applications are similarly deemed to be allowable, Applicants will file a terminal disclaimer in the present application.

The Rejections of the Claims Under 35 U.S.C. § 112, First Paragraph, Should Be Withdrawn

Claims 73 and 76 have been rejected under 35 U.S.C. § 112, First Paragraph, as containing subject matter that the Examiner contends is not described in a way as to reasonably convey to one of skill in the art that the inventors had possession of the claimed invention at the time the application was filed. These claims have also been rejected under 35 U.S.C. § 112, First Paragraph, as containing subject matter that the Examiner contends is not described in a way as to reasonably enable one of skill in the art to make or use the claimed invention. Because of the similarity of these rejections, they will be addressed together. These rejections are traversed for the reasons provided below.

As the basis for both rejections described above, the Examiner contends that although the claims recite the limitation "wherein said J chain portion is characterized in having the ability to bind to or facilitate binding to an epithelial basolateral factor," the Examiner states that the J chain by itself does not constitute an SC-binding site. In support of this argument, the Examiner refers to evidence cited of record in the Office Action mailed March 24, 2003 (pages 5-8 citing, *e.g.*, Brandtzaeg *et al.* (1977) *Ciba Found. Symp.*, 46:77-113), which the Examiner states is demonstrative of the fact that the J chain has a very low affinity for SC and cells containing native SC do not bind SC. The Examiner therefore concludes that a description of a J chain portion does not adequately describe or enable one of skill in the art to make and use a J chain portion that is characterized in having the ability to bind an epithelial basolateral factor.

A declaration under 35 U.S.C. § 132 is filed concurrently herewith. As outlined in the declaration, the evidence to which the Examiner refers not only involved flawed experimentation, but the data presented and discussed in such early publications do not determine if J chain does or does not constitute an SC binding site, only whether J chain is necessary for the binding of polymeric Igs to SC. As shown by the unpublished data described in the declaration, as well as research reports cited therein and submitted concurrently herewith

in an Information Disclosure Statement, available evidence contradicts the evidence cited by the Examiner and demonstrates that the J chain does bind SC. The Examiner is respectfully requested to review and consider the declaration and submitted evidence.

As Applicants have previously stated on the record, the present invention is based upon the surprising discovery that a J chain or derivative or variants thereof can specifically bind to a factor preferentially distributed on an epithelial surface (e.g., a basolateral factor)(see, e.g., page 8, line 23 to page 9, line 10 of the specification). In fact, the art cited by the Examiner underscores the non-obviousness of this discovery since it teaches away from the present invention. Applicants not only made this discovery, but also identified a fragment of the J chain that mediates this activity. Specifically, Applicants have identified that domain 2 is responsible for the ability to specifically bind to a factor preferentially distributed on an epithelial surface (e.g., a basolateral factor), and that domain 2 is characterized by a closed covalent loop containing at least three peptide domains having beta-sheet character, each domain separated from the other by a domain lacking beta-sheet character (see, e.g., page 12, lines 8 to 18 of the specification). As Applicants have provided clear evidence that J chain portions do bind SC, the Examiner's assertions that a description of a J chain portion does not adequately describe or enable one of skill in the art to make and use a J chain portion that is characterized in having the ability to bind an epithelial basolateral factor are now moot.

The Examiner also argues that it is unclear whether the polypeptide within claims 73 and 76 comprises: (i) a J chain encoded by nucleotides 1-213 of SEQ ID NO:8; (ii) a portion of a J chain encoded by nucleotides 1-213 of SEQ ID NO:8; (iii) a J chain; or (iv) a J chain portion encoded by nucleotides 1-213 of SEQ ID NO:8. The Examiner therefore interprets the claims as being directed to a portion of a J chain encoded by nucleotides 1-213 of SEQ ID NO:8, and states that this can encompass a single amino acid and therefore provides minimal structural or functional limits to the claims. As described above, the present claims have been amended such that they are directed to a targeting molecule that comprises a J chain portion encoded by nucleotides 1-213 of SEQ ID NO:8. Accordingly, this argument has been obviated.

In view of the evidence and argument provided above, the present claims satisfy the written description and enablement requirements of 35 U.S.C. §112, First Paragraph, and the Examiner is respectfully requested to withdraw these rejections.

The Rejection of the Claims Under 35 U.S.C. §102(e) Should Be Withdrawn

Claims 73 and 76 have been rejected under 35 U.S.C. §102(e) as being anticipated by Capra (U.S. Patent No. 6,063,905). The rejection is respectfully traversed for the reasons described below.

Capra discloses an IgA antibody consisting essentially of a VH domain fused to a first IgA1 C $\alpha$ 3 domain including a tailpiece, a VL domain fused to a second IgA1 C $\alpha$ 3 domain including a tailpiece, and a J chain, wherein the VL and VH domains constitute an antigen or hapten recognition site. The invention may further be defined as the dimers of the described minimal IgA antibodies formed by disulfide bonds between the monomers and the J chains and across the tailpieces. Capra therefore discloses a molecule comprising a J chain covalently linked via a peptide bond to an antigen combining site that does not contain any of C $_H$ 1 $\alpha$ , C $_H$ 2 $\alpha$ , C $_H$ 3 $\alpha$  and C $_L$ .

The Examiner argues that it is unclear whether the polypeptide within claims 73 and 76 comprises: (i) a J chain encoded by nucleotides 1-213 of SEQ ID NO:8; (ii) a portion of a J chain encoded by nucleotides 1-213 of SEQ ID NO:8; (iii) a J chain; or (iv) a J chain portion encoded by nucleotides 1-213 of SEQ ID NO:8. With respect to (ii), the Examiner states that a portion of a J chain encoded by nucleotides 1-213 of SEQ ID NO:8 could encompass a single amino acid. The Examiner therefore concludes that since Capra's molecule comprises a J chain (iii) that comprises at least one amino acid encoded by nucleotides 1-213 of SEQ ID NO:8 (ii), that Capra anticipates claims 73 and 76.

To anticipate a claim, a reference must teach every element of the claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). As described above, the present claims have been amended such that they are directed to a targeting molecule that comprises a J chain portion encoded by nucleotides 1-213 of SEQ ID NO:8 (iv). Capra does not teach use of a targeting molecule that comprises a J chain portion encoded by nucleotides 1-213 of SEQ ID NO:8. Accordingly, Capra does not meet all of the limitations of any of the pending claims, including claims 73 and 76.

Because Capra does not teach each and every element of any of the pending claims,

Applicants respectfully submit that this rejection under 35 U.S.C. §102(e) has been obviated and should be withdrawn.

The Rejections of the Claims Under 35 U.S.C. §112, Second Paragraph, Should Be Withdrawn

Claims 42, 52, 54-60, 62-65, 67-69, 73, and 76 have been rejected under 35 U.S.C. § 112, Second Paragraph, as being indefinite. This rejection has been obviated for the reasons described below.

The Examiner argues that it is unclear whether the polypeptide within claims 73 and 76 comprises: (i) a J chain encoded by nucleotides 1-213 of SEQ ID NO:8; (ii) a portion of a J chain encoded by nucleotides 1-213 of SEQ ID NO:8; (iii) a J chain; or (iv) a J chain portion encoded by nucleotides 1-213 of SEQ ID NO:8. As described above, the present claims have been amended such that they are directed to a targeting molecule that comprises a J chain portion encoded by nucleotides 1-213 of SEQ ID NO:8 (iv). Accordingly, this aspect of the rejection has been obviated and should be withdrawn.

The Examiner also argues that broad recitation of the term “biological agent” along with the narrower recitation of “antigen combining site” renders the claim indefinite because the biological agent is not limited to an antibody. As described above, the claims have been amended as suggested by the Examiner to remove the limitation to “an antigen combining site” (see Interview Summary attached to the Office Action of July 12, 2006). Accordingly, this aspect of the rejection has also been obviated and should be withdrawn.

**CONCLUSION**

In view of the aforementioned amendments and remarks, Applicants respectfully submit that the rejections of the claims under 35 U.S.C. §§ 112, First and Second paragraphs, and 102(e) are overcome. Accordingly, Applicants submit that this application is now in condition for allowance. Early notice to this effect is solicited.

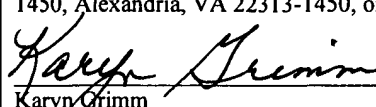
If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



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